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A framework for comparing N95 and elastomeric facepiece respirators on cost and function for healthcare use during a pandemic- A literature review[☆]

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ABSTRACT

SARS-CoV-2 has posed implications for personal protective equipment supply. In this literature review we examine if elastomeric facepiece respirators (EFRs) are effective substitutes for N95 respirators through comparing their functionality and cost. We reviewed 30 articles which researched the advantages and disadvantages of each respirator. We compiled the reported results and found, among other things, that users favour N95 respirators for comfort but prefer EFRs for protection. EFRs are more cost effective when N95s are used as designed (single use) but mixed strategies minimize costs when N95s are reused (as practiced during shortages). Future research is needed on multicriteria analyses and to incorporate SARS-CoV-2 specific data to support future pandemic planning.

1. Introduction

The worldwide outbreak of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has posed implications for the supply of personal protective equipment, and in particular, N95 respirators. Studies have shown that the airborne transmission of the virus is the dominant route for spread, ultimately increasing need for personal protective equipment (PPE) [1]. According to the World Health Organization (WHO), 89 million medical masks were required to meet monthly international demands [2]. N95 respirators were among the most highly demanded products, as they filter out 95% of penetrating particles with sizes between 0.1 to 0.3 micron [3]. With proper fit [4] and proper filter materials N95 respirators are effective for preventing airborne transmission of the virus [5]. This demand led countries like Canada to add the N95 respirator to their medical device shortage lists as manufacturers struggle to meet the need [6].

Several initiatives to manage equipment shortages in Canada were in place during the pandemic. For example, an interim order to accept imported protective equipment even if it did not meet Health Canada's pre- SARS-CoV-2 standards was signed to alleviate or prevent shortages (Government of [6]b). As well, Ontario Health submitted a

recommendations report which aimed to optimize the supply of PPE (Anderson, 2020). One recommendation was to stockpile reusable equipment such as elastomeric facepiece respirators (EFR) to help extend the supply of PPE.

Before further discussion, a brief description of EFRs and N95 respirators is needed. EFRs are tight-fitting respirators with facepieces composed of rubber or synthetic material. EFRs can be repeatedly used, contain replaceable filter cartridges, can be disinfected, stored, and reused [7]. N95 respirators are face masks composed of synthetic plastic fibres that protect against airborne particles but lose their facial seal after several hours of use. The main difference between N95 respirators and EFRs is that N95s are not intended for repeated or extended use.

When properly fitted, both EFRs and N95s are capable of protecting healthcare workers from airborne disease transmission and are essential PPE during SARS-CoV-2. The cost and function of both respirators, however, are quite different making the selection of the best respirator a challenging decision for healthcare organisations. This literature review explores previous EFR and N95 studies in this context. We aim to identify and review the state-of-the-art literature on their usability and feasibility in the healthcare industry. More specifically, we overview EFRs and N95s, review recent respirator research, and make

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recommendations for future research. There are several major findings discussed in the review such as methods for handling PPE shortages amid SARS-CoV-2, functional factors that impact patient care and user experience, and overarching benefits of implementing healthcare EFR programs. The findings underline capabilities and costs for analysis when determining whether organizations should invest in EFRs. This fundamental knowledge is needed for comprehensive economic analysis and comprehensive behavioural operational research studies.

The following search terms were used to locate articles for this study: *elastomeric respirators, effectiveness, patient care, filtration, feasibility, N95, simulation*. Variations of these terms were used to ensure exhaustive search results. The search was limited to peer-reviewed articles published between 2005–2023, with some exceptions. The searched databases include Science Direct and PubMed. Google Scholar was also used to locate open access articles. As overviewed in Fig. 1, the search results in 339 articles after duplicates were removed. Initial inclusion screening was completed by reviewing the title and abstract resulting in 100 articles. After reading these articles, 58 were deemed relevant for consideration in this review paper.

This paper is organized as follows. Section 2 further defines EFR and N95 respirators and further motivates the need for this review. Section 3 reviews papers discussing the function of each respirator with the purpose of defining the functional factors to consider when choosing between EFRs and N95s. Section 4 reviews papers discussing the costs of both respirators with the purpose of identifying the main cost factors to consider when choosing between these two respirators. Section 5 provides a summary of the findings, and finally, in Section 6 we conclude with an overview of the literature found and identified gaps.

2. Background

The following section provides a brief overview of respirator classes and subclasses. There are two classes of respirators that can be used

depending on the environment and level of protection required against contaminants. They are air-purifying (APR) and supplied-air respirators (CDC, 2021). The focus of this review is on air-purifying respirators which absorb air contaminants via a sorbent in a canister or cartridge. Respirators can have full-face, half-piece, quarter piece or mouthpiece forms. The mouthpiece form is uncommon and therefore is not included in this review. There are additional subclasses of APRs including: particulate respirators designed to withstand dust or mist; chemical cartridge respirators for different varieties of contaminants; gas masks which have greater protection than chemical cartridge respirators; and powered APRs. It is important to note that cartridges protect against gases and vapours, while filters protect against particulate hazards (i.e., aerosols such as mist, bacteria, or dust). Filters are equipped with filter material, while cartridges encase solvent material such as activated charcoal. Activated charcoal is used to protect against toxic vapours and is not required in a healthcare setting. The focus of the research is on particulate filters, as they are used in N95 respirators and EFRs.

There are a variety of particulate filters used in respirators which have a minimum filtration efficiency for different contaminants. N, R and P-series cartridges where N means not resistant to oil, R is somewhat resistant to oil, and P means strongly resistant to oil. Table 1 summarizes typical filters based the nine NIOSH classifications based on minimum filtration efficiency and type of aerosol. EFRs can use any of the

Table 1
Particulate filter classifications (NIOSH, 2014).

Minimum Efficiency	Oil Resistance Categories		
	N Non-Oil Aerosols	R Includes Oil Aerosols	P Includes Oil Aerosols
95%	N95	R95	P95
99%	N99	R99	P99
99.97%	N100	R100	P100

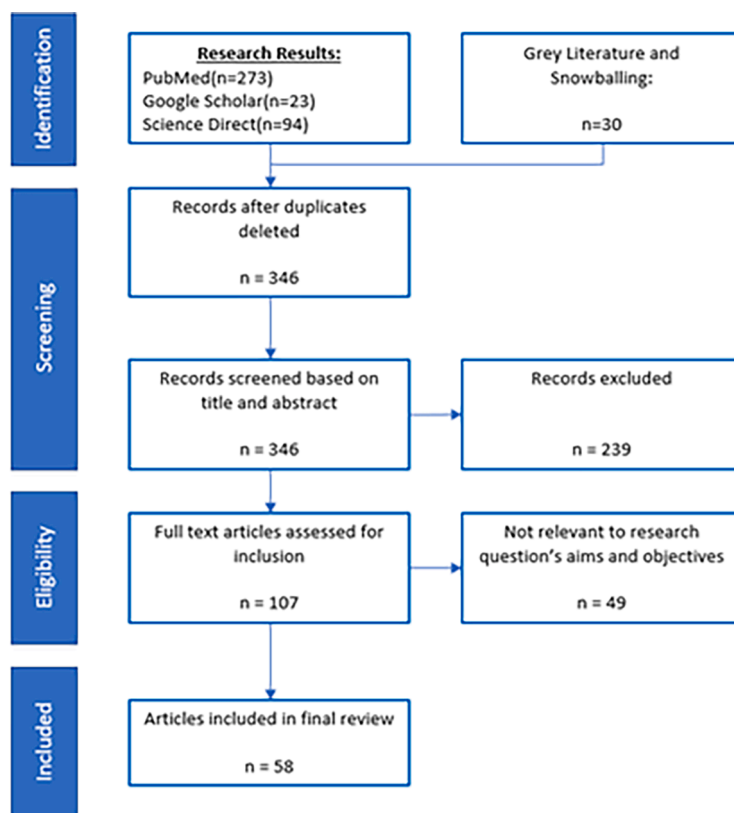


Fig. 1. PRISMA diagram.

particulate filters in Table 1. Further, they can utilize chemical cartridges or a combination of cartridge and filter depending on application safety requirements. Depending on the model and application, filters can last from eight hours of use (intermittent or prolonged) to several months once opened [7]. Filter and cartridge replacement is completed once breathing is strained.

In this review the choice being considered in healthcare is categorized to be broadly between EFRs (Fig. 2) using the P100 filter and N95 filter facepiece respirators (Fig. 3), as EFRs have the same basic requirements for an OSHA-approved respiratory protection program as N95s [7]. Both respirators have the 95 percent minimal level of filtration that is approved by NIOSH.

Therefore, N95s provide the minimum requirement for protection against SARS-CoV-2. As such, for the purpose of this review, EFRs are considered substitutes for N95s when preventing airborne transmission of SARS-CoV-2 [8]. For further discussion on the relative particulate filtering performance of these respirators see Zhuang et al. [9] who compared P100 filtered EFRs with N95s in a simulated workplace. Zhuang found that EFRs with P100 filters performed better than N95s potentially due to better fit given that EFRs have adjustable head straps.

3. Functionality

In this section we consider the functionality of N95 and EFRs. The manner in which these respirators are designed and used impacts user experience, user function and patient experience. User function and experience are investigated to understand the performance of a potential respirator program. Patient experience is also investigated because PPE policy changes impact how healthcare workers provide care.

3.1. Functionality Subfactors

Before SARS-CoV-2, Hines et al. [10] conducted two case studies on EFR programs in healthcare to outline functional factors of EFR usage. One case study was at the University of Maryland Medical Center (UMMC) and the other at the Texas Center for Infectious Disease (TCID). The case studies focussed on efficacy and effectiveness of half-facepiece EFRs, cleaning and disinfection, physiological and psychological considerations, and recorded experiences with EFRs. Several factors impacted the adoption of an EFR program such as N95 shortages during emergencies, presence of trained healthcare workers with experience and knowledge using EFRs, storage, risk perceptions and safety culture.

The case studies also identify key functional considerations of EFR use in healthcare. UMMC first adopted the EFR program due to perceptions of greater protection. However, the university stepped away from the program, as many EFR disinfection protocols were not followed



Fig. 3. N95 respirator [45].

due to the presence of problems with accessibility for mobile staff (i.e., physicians, respiratory therapists). Conversely, TCID adopted and maintained the EFR program by training staff, ensuring correct usage, maintenance, testing, and documentation of respirator usage. Several EFR weaknesses that the facilities highlighted were the fit of the respirators on oily skin, temperature discomfort, reduced communication abilities which negatively impacted patient care and the time required to clean the equipment. These findings show that there are components of EFR programs that influence program success because they impact safety, communication, and comfort.

Hines et al. [11] investigated the user acceptance of reusable respirators in healthcare in a more recent study. Healthcare staff enrolled in an EFR half-facepiece respirator program, a powered air-purifying respirator (PAPR) program or a N95 respirator program. After a period of use they answered questionnaires on beliefs, attitudes, and respirator preferences under different situations. It was found that N95 users highly favoured N95 respirators due to better communication and comfort in comparison to EFRs. However, EFRs were ranked higher by users when asked about sense of protection despite EFRs having equivalent protection to N95s, provided good fit. Lastly, for all users, EFRs were preferred in higher-risk situations. These findings provide evidence that EFR usage during SARS-CoV-2 may have higher user acceptance than expected. However, the study did not consider the impact of different healthcare training programs in place for respirator use which may have varying impacts on efficacy of EFR protection.

Hines et al. [12] also conducted a study that investigated the impact of EFR use on patient care by surveying 1152 participants from US hospitals and ambulatory services. The survey covered questions pertaining to respirator interferences in patient care, care activities and presence of patient fear. Results showed that only 16% of EFR users found their respirator interfered with patient care. In comparison, 17% of N95 users found their respirator negatively impacted patient care. Users rated EFRs “significantly more favorably with respect to sense of protection afforded” (p. 653), again, despite EFRs and N95s having similar protection. Given these findings, care providers may prefer more cumbersome PPE during SARS-CoV-2. In addition, this study provides indication that there is opportunity for improvements to reduce mask size and improve voice transmission for better patient care activities.

The research in Hines et al. [10], Hines et al. [11] and Hines et al. [12] indicate that there are possible circumstances in which the use of EFRs may be preferred over N95s. In contrast, it is also apparent that there are several prominent drawbacks of using reusable respirators that may have various impacts on choosing a PPE program strategy. To investigate further, several studies are reviewed with respect to comfort, communication, and safety. This framework is derived from Clever et al.



Fig. 2. Elastomeric respirator [44]

[13]'s whose definition of comfort, communication and safety as follows: Comfort concerns the experience of the user wearing the respirator and includes physiological and psychological strains. Communication factors include influences on speech transmission such as noise or enhanced features to improve user experience. Lastly, safety consists of several subcategories such as sterilization, training, and fit testing since they impact PPE efficacy and protection. The durability of the PPE is also listed, as it can be impacted by user adherence, length of use and reprocessing.

The remaining papers in this section are categorized by safety, comfort, and communication. This is used throughout this review as a framework for discussion and analysis. An overview of this framework is provided in Table 2.

3.2. Safety

Subcategories of safety include Protection and fit and Cleaning/Disinfection. Respirator fit directly impacts protection and whether the PPE is sealed i.e., if there is any leakage. Cleaning/Disinfection allows the respirator to be reused safely.

3.2.1. Protection and fit

What are the elements that impact respirator fit and do N95s provide better protection against hazardous particulates than EFRs? To answer this, consider research by Duling et al. [14] who investigated 5th percentile and random effects model methods for measuring performance of EFRs, N95s and surgical masks in a simulated workplace. They conducted six simulated work tasks with removal and redonning of the masks between each test and measured face seal leakage and filter penetration. The simulated tasks included breathing exercises, moving the head in several directions, repeating a message, and bending at the waist. It was found the EFRs had the highest protection, while surgical masks had the lowest protection. However, results were not consistent for each mask indicating the significance of standardized respirator fit tests. OSHA [15] considers both N95s and EFRs to have the same Assigned Protection Factor (APF) of 10, since with a correct fit test and seal, they can be safely used in an atmosphere that has a hazardous concentration of up to 10 times the Permissible Exposure Limit. However, further studies have shown that almost half of all healthcare professionals fail their second N95 fit test which occurs three months after their first test [16]. In addition, N95 masks have been found to lose aerosol protection within ten minutes due to loss of seal during routine body movements [17]. The discussed OSHA standards and studies are over 15 years old, suggesting that new evaluations of APF for each option is necessary. While EFRs and N95s continue to have the same APF, the incentive for healthcare organizations to use EFRs remains low.

An ASTM study investigating fit capability of full facepiece air-purifying respirators was conducted and found that the methods were appropriate if the fit factors were increased or the rigor of the test requirement was increased (Bergman, 2019). In addition, they concluded that not all users are similar, stressing the need for routine fit

testing and variable respirator sizes and designs. A study conducted in 2005 found that face length and lip length were not sufficient measures for N95 respirator fit testing [18]. Instead, face length and face width were recommended to be used for the half-face respirator fit test panel. OSHA has released a review of literature, citing that minimal facial hair is also required to achieve a sealed fit (Cichowicz, Shaffer & Shamblin, 2017). A more recent study indicates that facial hair must be removed to achieve a proper seal ([19], p. 94).

Another study investigated safety and protection of respirators during the SARS-Cov-2 pandemic by exploring possible N95 utilization strategies. De Perio et al. [20] focused on optimizing the supply of N95 respirators by reviewing engineer controls, administrative controls, and personal protective equipment controls. They recommended that research be completed to investigate utilization strategies such as using respirators that are past their shelf-life, decontaminated and reused, and worn for an extended period. As De Perio explains, respirator effectiveness relies on evaluation of fit testing and filtration, as well as determining the best PPE to avoid different modes of viral transmission. They recommended that further analysis be conducted on the length of time that SARS-CoV-2 remains infective in the air, and on respirator surfaces to understand modes of viral transmission. Chiang et al. [21] suggests that viral particulates may remain in the air for up to three days. However, Oswin et al. [22] found that airborne SARS-CoV-2 loses 90 per cent of its ability to infect people within 20 minutes.

Cleaning/disinfection. A significant difference between N95s and EFRs is that N95s are intended for single use, while EFRs are intended to be used repeatedly and for extended use, as they can be sterilized. Due to N95 shortages during SARS-CoV-2, cleaning, and disinfection of N95s was undertaken by many health providers and investigated by researchers to determine the number of times they could be reused. Fischer et al. [23] investigated ultraviolet (UV) radiation, dry heat, 70% ethanol and vaporized hydrogen peroxide (VHP) methods for decontaminating N95 facemasks over three contamination cycles. Findings indicated that VHP was most effective after all three cycles at deactivating SARS-CoV-2 while also maintaining the integrity of the facemask. This is consistent with Bergman's et al [24] evaluation of multiple VHP decontamination processing for facepiece respirators. UV was slower acting but can be used for two cycles. Dry heat was found to be effective for two cycles, while 70% ethanol was reaffirmed to be least effective due to the degradation of the N95 material, as previous studies have shown [25]. Other studies have indicated that N95s can be reprocessed up to 50 cycles with heat treatment (<85 °C) at various humidity levels without changing the filtration efficiency ([26], p. 6348).

Further, eight of 19 identified N95 decontamination techniques negatively impact fit and filtration ([27], p. 10). The 19 techniques are aerosolized peracetic acid, chlorine dioxide gas, commercial steamer, DiKlor-G sterilization, chlorine dioxide, dry heat (laundry dryer), dry heat (environmental chamber), electron beam irradiation, gaseous ozone, gravity steam, methylene blue, microwave generated plasma, moist heat, plasma discharge reactive oxygen species, Sterrad NX100 HPV/low temperature plasma, Stryker STERIZONE VP4 Sterilizer, supercritical carbon dioxide, ultraviolet germicidal irradiation (UVGI), UVGI and infrared heat and finally vapor phase hydrogen peroxide [28]. Schumm, et.al., [29] found that UVGI and VHP cause the least damage to N95 components.

A study completed by Ontiveros, et al. [30] also investigated sterilization methods for N95 layer material. They employed a commercially available UV surface device for use in hospital room settings. The materials used were a hydrophobic outer layer, middle electrostatically charged layers, and an inner biocompatible layer. The layers were preliminarily investigated to determine if combinations of the layers would impact results. The research concluded that it was not possible to penetrate all layers of N95 material without flipping throughout the sterilization process. In summary, researchers have found that the

Table 2
Summary of comfort, disinfection, and communication subfactors [13].

Comfort	Communication	Safety
Temperature discomfort	Muffling	Manual and automated reprocessing
Skin irritation	Environment factors	Fomite transmission
Respirator weight, harness, and size	Speech Intelligibility	User adherence
Breathing difficulty	Speech transmission index	Time burden
Carbon dioxide buildup	Hearing-impaired considerations	Durability
Anxiety and stress	Speech enhancing features	

number of times an N95 can be reused is between 2 and 50 cycles depending on, among other things, the cleaning and sterilization method.

While there are manufacturer protocols for disinfecting EFRs, there is a lack of research on disinfection protocols for routine use of EFRs in healthcare settings [13]. While Bessesen et al. [31] were able to identify a method for end-of-shift disinfection, it was noted that there are no universal standards for disinfection of different types of reusable respirators. Furthermore, higher concentrations of viral particles have been found in rooms where healthcare professionals remove PPE. In the case of SARS-CoV-2, viral particles can be detected in the air three hours after aerosolization [23]. Chiang et al. [21] deem EFRs to be safer than N95s because of this, as particles can get trapped in EFR filters and die over several days, reducing the number of filter replacements needed. Furthermore, EFRs contain separate inhale and exhale vents, preventing exhaled air to pass through the filter and aerosolize viral particles. This reduces the risk of transferring viral particles to others without PPE. One caveat of EFR use during sterile procedures is the need for a disposable surgical mask covering the exhale valve to maintain sterility ([32], p. 101).

3.2.2. Communication

Other factors impacting patient and user experience have been investigated, such as the diminished speech intelligibility associated with different respirators by healthcare workers. By using the modified rhyme test, speech intelligibility was assessed in an intensive care unit environment and results showed that, a) respirators decreased speech intelligibility by a range of 1-17% (which the authors deemed to be insignificant), b) EFRs with voice augmentation equipment was associated with higher speech intelligibility and, c) powered air-purifying respirators (PAPR) produced hearing clarity of 79% compared with 90% with no PAPR [33]. However, the results of the study indicated that the odds of correctly hearing a word spoken by an individual wearing an EFR in a healthcare setting is lower on average than if alternatives were worn. A solution offered in the paper was to use half-face EFRs with voice augmentation devices to support better speech intelligibility. It is also important to consider speech and audibility requirements on a case-by-case basis. For example, Wentworth et al. [34] considered a transparent EFR design to address hearing-impaired needs in the healthcare community. In their review of N95 use, Baig et al. (2009) indicate potential for job and communication interference. Whichever PPE is chosen, NIOSH [35] requires at least a 70% pass rate for the modified rhyme test.

3.2.3. Comfort

Comfort and Anxiety can have various impacts on patient care and the user experience and can be measured by the State-Trait Anxiety Inventory (STAI) [36]. In a review by Johnson [37] anxiety was stated as the “most important threat to equipment wear” (p. 8). A study by Wu et al [38] investigated user experience by comparing anxiety metrics of EFRs in comparison with N95 respirators. Using the STAI, twelve volunteers with normal to mildly impaired respiratory conditions performed simulated work tasks wearing N95 and EFRs. The anxiety effect of the respirators was measured. It was found that N95 had no observed impacts, while the EFR increased state anxiety by 2.92 units, ($P < 0.01$). Overall, the authors did not deem the increase to be significant. There are several causes for anxiety during the use of respirators in the study such as claustrophobia, laboratory testing and methods, workplace circumstances and some respirator designs. When comparing anxiety during use of each respirator, it was noted that it may have been possible that N95s reduced anxiety, while EFRs increase anxiety. One drawback of the study was that the sample size was small, however it provides evidence that measuring anxiety in individuals may help PPE selection processes.

Similar findings concerning comfort have been discovered when investigating EFR modifications in attempt to handle N95 supply

shortages during pandemic settings. For example, Liu et al. [39] studied the new design of EFRs using custom anaesthesia circuit filters to address possible EFR filter shortages when N95s are replaced with EFRs. The research was conducted on eight volunteers, while measuring their fit testing, respiratory rate, and end-tidal carbon dioxide using the circuit filters. The findings of the study indicated half of the volunteers felt discomfort, while a small portion felt facial pressure and one participant felt dizziness. The study concluded that the adapted EFR may be a suitable substitute for disposable N95 respirators. However, future recommendations for research exploration were offered. It was recommended that a larger sample size be used, more than one filter be tested and modifications for larger users be investigated. Ultimately, EFRs and circuit filters may replace N95s during pandemics, but comfort factors still need to be addressed.

3.2.4. Other

Some studies have investigated other user functions of N95 and EFRs. Given SARS-CoV-2, the Centre of Disease and Control provided guidelines for the reuse of N95s to combat PPE shortages [40]. N95 respirators are advised to be used for less than eight hours of continuous use, while a single EFR may replace thousands of new reusable N95 masks. Design improvements for EFRs were investigated and three different filtering facepieces in comparison to 3M 1860 and 1870 N95 respirators. Participants were asked to self-report tolerability on comfort, wearing experience and function of the new PPE prototypes after simulated healthcare work tasks. All prototypes had high tolerability except for the EFR hybrid improvement that was designed with centralized, vertical filter housing and no exhalation valve. Communication and function capabilities interference were cited as the leading causes for low tolerability of EFRs in comparison to controls and other filtering facepieces [41].

4. COST CONSIDERATIONS

There are several functional benefits and drawbacks of EFRs compared to N95s, as discussed in the previous section. However, when determining whether to invest in EFRs, costs must also be considered. There are a few studies on the cost differentiation between respirators and several studies have explained the need for more comprehensive economic evaluations of respirator alternatives to guide decision-makers [42]. Comparisons may be made for EFRs and the prolonged or repeated use of N95s. Likewise, comparisons may be made if N95 disinfection protocols are adopted. The prolonged use and reuse of N95s reduces the quantity required, subsequently reducing upfront and inventory costs. Generally, the costs used for comparisons can be categorized into three groups: equipment, inventory, or program expenses. A study by Baracco et al. [43] determined the circumstances in which stockpiling EFRs, N95s or a mixed strategy was most cost-effective. Factors and costs that were considered for Baracco's analyses can be found in Table 3.

Table 3
Summary of costs and factors to consider when comparing respirators.

Category	Item	Factors
Equipment	Unit cost of N95	Extended use of N95
Equipment	Unit cost of EFR	Repeated use of N95
Equipment	Filter costs	Size of target population
Inventory	Lease cost	Shelf life
Inventory	Insurance cost	Dimensions of PPE storage
Inventory	Inventory management salary	Dimensions of PPE storage
Program	Mixed strategy costs	Number of filter sets required per EFR
Program	Fit testing costs	Fit test duration
Program	Training costs	Number of respirator users
Program	Disinfection costs	Number of patient interactions
Program	Disinfection materials	Training duration
Program	Disposal costs	Data-driven policy development

Factors in Table 3 include those impacting equipment, inventory, and program implementation. As discussed, N95s may be used repeatedly or for extended use to alleviate shortages. In addition, the size of the target population, number of healthcare workers, and frequency of patient interactions should be known to estimate the quantity of EFRs or N95s for a respiratory protection program. Once demand is known, inventory costs must be considered. Storage requirements can be estimated by determining size and volume of PPE and filters. Inventory costs are also incurred for conditioned space to allow for control of humidity and temperature necessary for storing PPE. Lastly, program costs that include training, fit testing and disinfecting must be considered. Cost factors for the PPE program include materials and time needed to plan, implement, and evaluate training, testing, and disinfection.

4.1. Studies comparing EFR and N95 respirators

There are several studies that share the same objective in comparing EFRs with N95s to reduce costs. It is apparent that there are possible instances in which it may be advantageous to use one PPE over another due to financial constraints.

Baracco [43] determined the costs and benefits of stockpiling EFRs and N95s in a pre-SARS-Cov-2 and theoretical pandemic setting, as summarized in Fig. 4. Assumptions made were that healthcare workers worked 40-hour weeks for 12 pandemic weeks, with two infected patient contacts per hour on average; a 40% attrition rate to account for the loss of healthcare workers due to illness, refusal to work or familial reasons; 40% and 20% infection rates in adults and children respectively, and an average stay at a hospital of five days and ten days for patients requiring intensive care unit treatment. Overall, findings showed that EFR respirators were least costly when used for extended periods of time. Otherwise, an N95 program is least costly when the

equipment is used between 4 and 8 hours.

Extensions to Baracco [43]'s model are necessary to account for what was learned and experienced during the current SARS-COV-2 pandemic. These could include the costs of the disinfection, training, and testing components of an elastomeric respirator program. The costs associated with the reuse of N95 masks after decontamination through UV light or alternative methods which were developed for SARS-Cov-2. Lastly, salvage costs can be considered, as it may be necessary to investigate the disposal costs of PPE. The additional costs associated with new alternatives can be incorporated into an improved comparison model.

Chalikonda et al. [46] investigated the implementation of a new cost-effective EFR program as well, as many healthcare facilities were challenged with N95 shortages during the SARS-CoV-2 pandemic. Chalikonda used a clinical allocation strategy to replace N95s with EFRs using P100 filters. The strategy consisted of an operational plan to educate users, fit, test, and sterilize masks. Within one month, 90% of N95 respirators were replaced at a cost that was ten times less than the original N95 program. In addition, the cost benefits increased the longer the EFRs were used. One challenge in the study was that staff members who did not pass seal checks did not graduate to fit testing and were required to continue wearing N95 respirators or powered air purifying respirators. The authors concluded that further research is needed to ensure successful seal checks for all staff members. Additionally, user preferences, physiological and psychological factors associated with wearing EFRs were not considered.

4.2. Equipment and Inventory Cost

For further considerations of respirator costs, the following section provides a breakdown of research that considers inventory, equipment, or PPE program costs but does not directly compare EFRs and N95s.

A study by Mukerji [47] investigated N95 cost effectiveness in a Chinese healthcare facility. The analysis was done to determine whether the continuous use of N95s should be chosen over general face masks. Continuous use means use of an N95 respirator for an entire shift. The metric of interest was the incremental cost-effectiveness ratio per clinical respiratory illness (CIR) case prevented. Costs included for analysis were absenteeism, intervention, and healthcare worker CIR case costs. The majority of the considered costs were related to N95 program implementation and equipment requirements. For example, productivity costs related to time for fit testing for different healthcare workers (doctors, nurses, and administrative staff) were considered which impact comparisons of PPE programs. Notable results from the research indicate that the incremental cost to prevent a CIR case in a healthcare worker using N95s ranges between US \$490 - \$1,230. If fit testing is included in the program, the cost doubles. It was also cautioned that the results from the study may not be transferable between countries due to differences in factors such as productivity.

A study by Patel et al., [48] is a more recent cost analysis for reusable respirators. A comparison was completed for reusable respirators and single-use filtering facepiece code 3 (fluid resistant) masks. Initial outlay, recurring costs, patient costs, weekly costs, and cumulative costs were identified and totalled to underscore the savings in adopting a reusable respirator program. Patient costs considers whether a disposable mask is used per patient or continuously for a maximum of one hour. If a reusable respirator is used, wipes are required for disinfection and prevention of disease spread. The cost savings were found to be £150 (261.50 CAD) per month. One prominent functional factor (not already discussed) was the utilization of hydrocolloid dressing to improve comfort during prolonged use of reusable respirators.

4.3. Program Costs

To outline common program costs, we overview the National Institute for Occupational Safety and Health's [49] toolkit which provides a guide in forming a respiratory protection program (RPP). A first step is

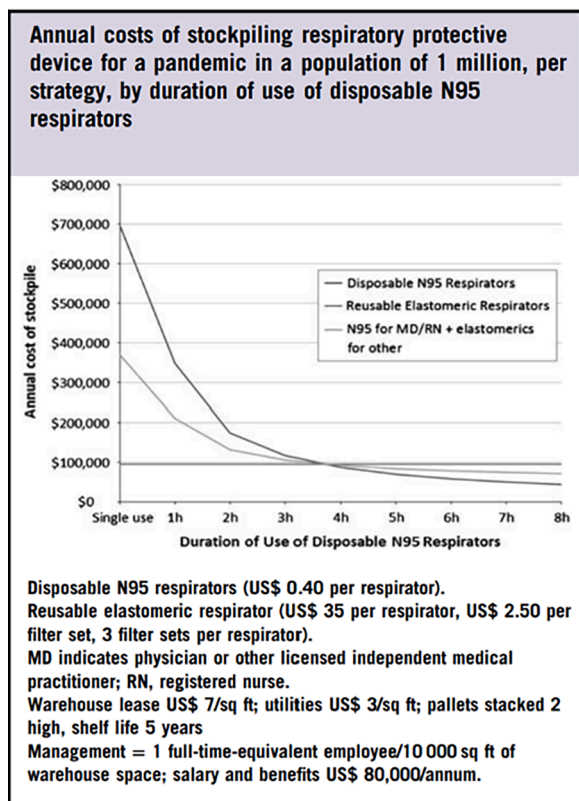


Fig. 4. Annual costs of stockpiling respiratory protective device for a pandemic in a population of 1 million, per strategy, by duration of use of disposable N95 respirators [43].

to identify a program administrator responsible for hazard evaluations and procedure and policy adoption. The second section of the toolkit covers hazard evaluation. The purpose of the evaluation is to identify if there are hazards in the workplace, how often the hazards are present and whether respiratory protection is needed.

The last section of the program development covers policies guiding the general operations of a respiratory protection program. Respirators require routine inspection, as well as routine training/inspection to ensure proper use (donning and doffing). Similarly, it is important to determine storage, maintenance, repair, and disposal procedures. Are respirators repaired in house? Who has the responsibility of disposing of equipment?

The policies section also summarizes considerations for RPP training, recordkeeping, and program evaluation. Training is necessary for the success of the RPP. The program should provide an outline of the training curriculum and how principles of the program will be taught. The main objectives of the course should be to educate on hospital practices and program risks, how to properly use respiratory equipment, and how to determine when respirators or filters need to be disposed. In regard to recordkeeping, several documents should be maintained. The documents are the written program itself which should be available to all participants, the medical evaluations of those using (and not using) PPE, fit tests, checklists, changes to the program and evaluation records. Program evaluation records are the last consideration of the RPP development section of the NIOSH toolkit. A checklist is offered but serves as a starting point for any developing RPP. The evaluation should consider feedback from respirator users and document any aspects of the program that is not being followed. It must also offer a section on how the program will be assessed and how the program will be re-evaluated as necessary (does not need to be at set intervals).

4.4. Intangible Costs

In addition to a well functioning respiratory protection program, successful implementation depends on staff participation and buy-in. These have costs but they are typically considered intangible costs because they are difficult to quantify or estimate. Brown et al [50] outlines five key findings related to RPP evaluations and success. The first finding was that safety climate is a prominent indicator of the success of hospital RPPs. The second finding was that annual fit test tracking was lacking. This is an important finding, as ongoing evaluation is needed to ensure continued success. Point-of-care PPE monitoring is suggested to ensure proper use of respiratory equipment. Another finding was that end-user feedback was lacking, indicating failure to implement a mechanism for routine evaluation. Lastly, it was found that users were unclear on choosing and using equipment, as well as when to use equipment. This may reflect on the hazard assessment and program training components of the RPP.

A leading indicator of RPP success is the organizational safety climate. According to a report by Clever et al. [13] safety culture is perceived differently by different people in different roles. However, there are several ways in which safety culture can be strengthened and standardized. The first is to strengthen leadership and management commitment to safety. In addition, it is important to ensure safety resources and alternatives are easily accessible. An organization that fosters open conversations about safety and promotes learning from past mistakes establishes a safety culture founded on continuous improvement. There are other components of safety culture change discussed in the report, which are: investment, participation, assessment, capacity, and communication ([13], p. 142). Investment considers notable aspects such as setting share priorities. Without participation of employees and management, a safety culture cannot be established. Goals, problems, and progression are also important in the assessment of the RPP and safety culture. Lastly, capacity encompasses the training and facilitation of safety procedures, while communication must be regular, reliable, and complete.

Establishing an RPP and a safety climate helps to ensure the success of the chosen respiratory equipment. When determining when EFRs are suitable substitutes for N95s, considering additional program factors is necessary to ensure successful implementation and administration. Though there is not a lot of literature on EFR programs, current toolkits and standards can act as templates for unique case-by-case program development.

5. Summary

To summarize findings of the articles reviewed in Sections 3–5 three tables are presented. Table 4 overviews papers considering both N95 and EFRs. Articles considering only EFRs are overviewed in Table 5 and likewise, articles considering only N95s are overviewed in Table 6. The tables summarize study methodology, and findings on costs, safety, communication, and comfort. An additional column indicates gaps in the literature and list either the limitations identified in the research or opportunities for further investigation.

Table 4 provides a summary of the literature on comparisons of EFRs and N95s. Given the summary, it is apparent that studies are either attentive to functionality or cost of PPE, but do not extensively investigate both. Further, comparison studies on functional factors of respirators are more frequent than those comparing costs. Each study considers equipment, program, and inventory costs of stockpiling EFRs, N95s and alternatives.

Similar results are evident for all three cost-comparing studies, indicating EFRs can be more cost-effective than N95s. However, a common theme among study limitations is that functional factors such as comfort and protocol adherence negatively impact the roll-out of EFR stockpiling programs. Furthermore, estimation methods for PPE demand often do not consider needs for additional healthcare workers during peak pandemic demands. Demand of PPE was estimated using different respirator utilization strategies such as comparing EFR use with prolonged use (8 hours) of N95s. Each model is different in demand assumptions and respirator utilization strategies. For models that consider both functionality and feasibility, no applications were available to calculate the cost and functional benefits of both EFR and N95 investments.

The remaining comparative studies in Table 4 focus on safety, communication and comfort factors impacting the usage of N95s and EFRs. A theme among functional comparison studies is that fit testing and training are essential safety factors in respiratory protection programs in healthcare. For both N95s and EFRs, periodic fit testing is required to ensure protocol adherence. Continuous education is also considered to ensure PPE is used safely and effectively. A prominent finding in safety comparisons is that EFRs are preferred in emergency settings due to better sense of protection against facial seal leakage.

There are several trends for comfort and communication factors in the comparison studies. First, healthcare workers prefer N95s over EFRs due to comfort and communication. With regard to comfort factors, EFRs have a higher negative impact on users and patient anxiety due to design. Additionally, skin irritation and prolonged use discomfort are cited as contributors to N95 preference over EFRs. Secondly, though EFRs pass NIOSH modified rhyme test requirements, poor speech intelligibility appears several times in the literature as a factor negating EFR use. Recommendations in comparison studies list EFR design improvements or alterations to enhance comfort and communication. When choosing a respirator program, it is important to consider functional requirements on a case-by-case basis.

Table 5 provides a review of EFR research and identifies unique research focussing on EFRs alone. Literature on EFRs often investigates safety factors. One safety factor under scrutiny in many EFR studies is disinfection. Disinfection protocols are not reliable without training and periodic testing as noted in Table 4. Standardized processes are necessary to ensure consistent and effective disinfection necessary for preventing spread of contaminants. In relation to protocol standardisation,

Table 4
Summary of research considering N95s and EFRs

Paper	Methodology	Cost	Function Safety	Comm.	Comfort	Limitations/Gaps
Considers EFRs and N95s						
[43]	- Pandemic modelling - Cost comparisons	- Mixed strategy (N95 and EFR) vs EFR vs N95 vs powered APR - Extended vs mixed use	- Fit tests - Training	–	–	- Only considers a constant number of disease cases and healthcare practitioners
Chalikonda et al. [46]	- Multimodal training approach - Hood and sensitivity solution fit testing - Cost-ratio assessment	- Comparing N95 and EFR with filters - Phased program approach	- Fit tests - Dis-infection flowcharts - Training	–	–	- Does not consider user functions
[21]	- Descriptive research	–	- Fit and seal comparisons - Reuse and disinfection comparisons - Fit testing - Duration of use and type of movements	–	- Extended EFR use causes discomfort	- Lacks clinical workplace settings investigation
Duling et al. [14]	- Simulated workplace protection - Bitrex Solution Aerosol Qualitative Fit Test - Saccharin Solution Aerosol Protocols - Ambient Aerosol Condensation Nuclei Counter Quantitative Fit Testing Protocol factor testing	–		–	–	- Simulated workplace exercises may not reflect real workplace and respirator protection
He, 2015	- Simulated workplace protection factor testing	–	- Fit test and leakage	–	–	- Study aerosol may not have same properties as flu
[10]	- Interviews to determine adoption and continued use of EFRs in hospital settings	–	- Success of EFR program depended on safety culture and certified safety professionals	- Communication impairment with EFRs	- Less skin irritation with N95s - EFRs recorded to be more constraining	- Small sample size - Interviewed authoritative figures only - No extensive cost analysis
[11]	- Cross-sectional survey for evaluation of healthcare practitioner EFR, N95 & powered APR use	–	- Sense of protection evaluation - Fit testing and training	- Survey response evaluation of communication	- Survey response evaluation of comfort - Confidence evaluation	- Evaluation of different sites: different training programs - No extensive cost evaluation
[12]	- Interviews and electronic surveys	–	- Respirator interference with patient care	–	- Responses reflected patient anxiety	- No information of specific tasks or emergency settings
[32]	- Considerations of different PPE	–	- Protection against aerosol-generating procedures	–	–	- Missing cost considerations
[48]	- Cost analysis - Comparison of cumulative costs	- Initial outlay - Recurring costs	- Fit testing - Wipes for disinfection	- Suggested EFR use: short phrases and low noise	- Suggested EFR use: hydrocolloid dressing	- Does not include healthcare worker costs
[33]	- Modified rhyme test result comparisons	–	- Training and fit testing (NIOSH)	- Evaluation of intelligibility of words	–	- Small sample size - No cost analysis
[38]	- Simulated work task analysis - State-Trait Anxiety Inventory - Trait anxiety measurements	–	–	–	- Comparison of anxiety between N95 and EFR (EFR induces greater anxiety)	- Larger population needed to determine if subpopulation has differing responses

the literature continues to emphasize the importance of ongoing training and program auditing to prevent protective respiratory program failure.

Additional functional and feasibility trends are seen in EFR literature. As discussed, EFR design changes are often recommended when considering comfort and communication factors impact user experience. Clever [13] dedicates a section of their consensus study to research and design of EFRs to enhance speech intelligibility and reduce design aspects that cause discomfort. Aspects include size and weight of respirators, and ease of donning and doffing the equipment. With regard to feasibility, EFRs generally cost more than most other PPE but can have

considerable benefits as indicated by comparison studies. Though there is research offered on costs of new EFR designs to address N95 shortages during SARS-CoV-2, further investigation into communication is necessary.

Table 6 provides a review of literature on N95s. Literature on N95s is predominantly based on safety. For example, a theme in N95 research is determining optimal methods for decontamination to reduce the quantity used and subsequent costs (utilization strategies). With decontamination methods, N95s can be used for longer periods of time, and repeatedly. However, though decontamination methods are offered in

Table 5
Summary of literature on EFRs.

Paper	Methodology	Cost	Function Safety	Comm.	Comfort	Limitations/Gaps
Considers EFRs only						
Bessesen et al. [31]	- Disinfection standard operating procedure (SOP) development - Error rate comparison of manufacturer instructions and SOPs		-Disinfection protocols - Fit testing (Occupational Safety and Health Admin)	–	–	- Bleach concentrations are not consistent across products
[50]	-Respiratory Protection Program admin questionnaire - Walk-through questionnaire - Discussion Group Questions	–	- No structured auditing process for protocols - Disinfection and fit testing protocols not standardized across hospitals	–	–	- Only one hospital out of nine in the study used EFRs consistently
[13]	- Consensus study - Case studies compilation	- Stock-piling costs - Compare costs	- Safety culture changes - Fit testing - Disinfection - Training and testing	- Factors impacting comfort and tolerability - User tolerability - Speech intelligibility	- R&D: next generation of EFRs to improve comm.	- Indicates expansion of research on cost-analysis training, fitting, use
[27]	-Literature review -Challenges vs benefits of EFR adoption	-Cost over time	-Disinfection -Training and test fitting		-User discomfort	-Much of the research is limited to hospital use, not considering long-term care, outpatient settings, etc.
[39]	- Design feasibility study - Quantitative fit testing: end-tidal CO ₂ and respiratory rate	- New design - Custom production costs	- Fit tests	- Muffled communication	- Dis-comfort	- Need for investigation of higher BMI users
Wentworth et al. [34]	- Multi-institutional trial of transparent EFR	–	- Design allows for better seal	- Design for hearing-impaired persons	- Design improves comfort and maintains seal	- Sample size of study was small

the literature, there is no standard, universally used method and respirator durability is not guaranteed. Another safety trend in N95 investigations is the success of fit testing. N95s are not effective if worn incorrectly and require routine fit reassessments to prevent leakage. This theme aligns with the EFR and comparisons findings. Finally, while safety plays a large role in PPE, much of the studies listed in Table 6 are clinically based. Further investigation of usage in the workplace is suggested.

Of the N95 literature, there are two studies that investigate feasibility of N95 programs. Studies often use cost-effective analyses as methodology, though they use different metrics to estimate benefits. Metrics include total program cost, level of intervention acceptability, incremental cost of preventing a clinical respiratory illness or net savings compared to no intervention, to name a few. A limitation of these metrics and economic evaluations is that results or methodology are often not transferable between settings. A comparative analysis among respirator types is preferred due to this, as PPE comparisons do not require factors such as country-specific levels of intervention acceptability. One limitation of N95 costing related to safety is utilization strategies that allow for repeated use or prolonged use of N95s. Decontamination of N95s is still in research phases and there are no publicly accepted standards. N95s are typically used once per patient or up to 8 hours if the seal does not break.

Overall, EFRs are the preferred option in emergency settings since fit is the primary determinant of respiratory efficacy as long as the respirator is equipped with proper filter material that meets NIOSH and OSHA regulations. N95s lose fit with longer durations of use, and reuse with disinfection methods. More frequent EFRs usage is recommended to be phased into healthcare to support the stockpiling of alternative N95 personal protective equipment in the event of future infectious disease outbreaks. In addition, more frequent use of EFRs supports future roll outs of disinfection and maintenance programs during emergency settings, as more healthcare professionals become experienced in the processes.

In determining whether EFRs should be used for routine healthcare

or just stockpiled for emergencies, it is recommended that EFRs should be stockpiled for emergencies and be used in conventional settings when supply of N95s do not meet demand. However, considerations of using EFRs for routine healthcare include the need to replace components such as straps, valves, filters, etc. In addition, for reuse, EFRs still require disinfection, as well as maintenance regardless of whether they are used for surge or routine use.

6. Discussion

Future pandemic planning is important in ensuring enough PPE is available for usage in healthcare settings, avoiding many of the challenges endured during SARS-CoV-2. When considering which PPE to invest in, several recommendations should be considered, which are based on the literature within this paper:

- EFRs may be preferred in emergency settings as users perceive them to offer better protection.
- Programs that consider different PPE utilization strategies are benefited if training, protocols, and costs associated with required materials and time are considered.
- Materials and time costs required to disinfect PPE should be considered in cost analyses.
- Education and auditing systems are necessary for ensuring procedure adherence and continued program support and must be developed before RPP implementation.

These recommendations address the importance of combining functional and financial considerations when developing cost-effectiveness models for PPE comparisons. Most of the reviewed papers investigate respirators in a hospital setting but the conclusions and recommendations are applicable beyond hospitals in general healthcare settings such as outpatient clinics, dentist offices, etc.

The purpose of this paper is to review literature comparing the capability and cost considerations for determining whether

Table 6
Summary of literature on N95s.

Paper	Methodology	Cost	Function Safety	Comm.	Comfort	Limitations/Gaps
Considers N95s only						
[51]	- 63-item survey	–	- Preference for disposable respirators	- Little interference in comm. With patients	- Preference for respirators that do not interfere with breathing	- Findings indicate need for research into new design of N95
[24]	- Decontamination methods (3 cycles): ultraviolet germicidal irradiation, ethylene oxide, hydrogen peroxide gas plasma, hydrogen peroxide vapor, microwave oven generated steam, bleach, liquid hydrogen peroxide and moist heat incubation	–	- Disinfection and respirator degradation	–	–	- Did not test FFR filtration efficiency of actual bioaerosols following a treatment
[20]	- Descriptive study design	–	- Fit tests	–	–	- Expired equipment effectiveness
[23]	- Decontamination methods: ultraviolet radiation (260 – 285 nm), 70° C heat, 70% ethanol and vaporized hydrogen peroxide (VHP)	–	- Fit tests - De-contamination durations - VHP likely best method	–	–	- No cost analysis - Did not study different models of N95s
[28]	-Fit factor measurements -19 disinfection methods investigated: aerosolized peracetic acid, chlorine dioxide gas, commercial steamer, DiKlor-G sterilization, chlorine dioxide, dry heat (laundry dryer), dry heat (environmental chamber), electron beam irradiation, gaseous ozone, gravity steam, methylene blue, microwave generated plasma, moist heat, plasma discharge reactive oxygen species, Sterrad NX100 HPV/low temperature plasma, Stryker STERIZONE VP4 Sterilizer, supercritical carbon dioxide, ultraviolet germicidal irradiation (UVGI), UVGI and infrared heat and finally vapor phase hydrogen peroxide	–	-Fit tests -De-contamination	–	–	Interpretation and potential translation of results - it is still unclear if observed changes in strap tensile force has a downstream influence on FFR fit.
[25]	- Decontamination methods: microwave-generated steam, warm moist heat, and ultraviolet germicidal irradiation (UVGI) at 254 nm	–	- Fit testing and impact on protection after treatment	–	–	- Properties such as biocidal efficacy, pressure drop, residual toxicity needs to be evaluated
Lee, 2005	- H1N1 influenza contamination - Prospective observational cohort study - Standard fit-test protocol analysis - Qualitative fit-test protocol employing denatonium benzoate	–	- Impacts of training and fit testing on respirator protection	–	–	- No cost analysis - Small sample size and no cost analysis
[26]	- Heat under various humidities vs steam, vs 75% alcohol vs chlorine vs UV germicidal irradiation	–	- Heat is most effective	–	–	- Did not test on respirators contaminated with SARS-Cov-2
[42]	- Scopus database literature search - Inclusion of cost-effectiveness studies	- Productivity costs - Healthcare provider costs - Economic costs of productivity losses	- Studies including assigned protective factor	–	–	- Inclusion criteria limited number of studies
[47]	- Cost-effectiveness analysis - Incremental cost-effectiveness ratio (ICER)	- Equipment - Admin. - Product. Costs -Fit test costs	- Continuous use of N95s - Fit testing vs no fit testing	–	–	- Costs and factors may not be similar across countries
[30]	- UV disinfection system	–	- UV penetration - Disinfection	–	–	- Layer disinfection does not reflect reality
[3]	- Filtration efficiency testing	–	- Filtration protection - Patient care interference	–	- Testing with low pressure drop for breathing	- Testing was limited to two bacteria
[41]	- Randomized simulated workplace study	–	- Fit test - Effect on attention	- Muffled speech - Difficulty hearing	- Dizziness - Fatigue -Breathing -Skin irritation -Workload induced heavy breathing	- Other costs and market considerations impact respirator adoptability
[17]	- Quantitative fit test - Ambient air particle concentration measurements	–	- Face seal leakage and fit testing	–		- Need for frontline workers investigation

(continued on next page)

Table 6 (continued)

Paper	Methodology	Cost	Function Safety	Comm.	Comfort	Limitations/Gaps
[9]	- Simulated workplace protection factor testing - Facial measurements - Sex-stratified analysis	–	- Face seal leakage and fit testing	–	–	- Only considers respirator and facial dimensions as design factors

organizations should invest in EFR and N95 respirators. There are several important aspects of the existing body of literature discussed. Aspects include accepted N95 disinfection methods, clinical allocation strategies that reduce costs by implementing EFR programs, user functional weaknesses such as fit test, communication challenges and time consumption during PPE disinfection. In addition, N95 users highly favour N95 respirators due to better comfort but prefer EFRs under circumstances when a greater sense of protection is desired. Lastly, studies have suggested that EFRs are safer than N95 respirators and EFRs typically do not have significant negative impacts on patient care. If N95s and EFRs are to be compared in research, it is important to understand the functional strengths and weaknesses of each, including the shelf-life, decontamination methods and limitations in previous research.

When considering protection ratings, EFRs and N95s are arguably equivalent, however, duration of usage directly impacts fit and seal which is detrimental in maintaining respiratory protection. In this regard, EFRs have an advantage due to more adjustable components as highlighted by Zhuang et al. [9]. Perhaps, APFs should be based not only on the type of mask and mask size, but typical duration of use before leakage.

The Baracco [43] study was the most comprehensive that we identified. The model considered moderate and severe pandemic circumstances based on the 1918 H1N1 pandemic (severe) and 1968 H3N2 pandemic (moderate). The features of the model can also be used to help determine pre-SARS-CoV-2 and post-SARS-CoV-2 circumstances such as fatality rate, average length of hospital stay, etc. The model could be updated to reflect SARS-CoV-2 attack rates and hospital conditions that impact the number of healthcare worker and patient contacts. For example, many health providers postponed elective surgeries in preparation of the expected pressures of SARS-CoV-2 on the healthcare system [52]. A comparison of N95 and elastomeric respirator use should be conducted for the SARS-CoV-2 pandemic setting and post-pandemic setting in which respirators will continue to be necessary. According to a primary care professor at the University of Oxford, masks will be a requirement until there are no new cases (Greenhalgh, 2020 as cited in Khazan, 2020).

The current state of the literature reviewed is quickly developing as SARS-CoV-2 persists and new challenges in healthcare continue to put pressures on resources and patient care. Many new studies (published in 2020, 2021) provide insights into immersing functional and financial requirements of PPE. However, there are some significant gaps in existing knowledge. Models discussed use dated data from previous pandemics. New factors such as disinfection methods extensively researched and policy changes such as disinfecting N95 masks should be considered. Furthermore, many studies are completed in controlled environments. It is important to conduct user case studies in clinical environments to better understand potential design improvements of EFRs for better program acceptance and maintenance. In conclusion, areas for future study include feasibility analyses that take a system approach at investigating combined financial and functional factors of EFR and N95 respirators. Existing research sets the path for development of a new feasibility model for EFRs based on SARS-CoV-2.

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